

**REMARKS**

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application, in accordance with 37 C.F.R. § 1.112, are respectfully requested.

By the foregoing amendment, claims 10 and 17 have been amended to recite that the amount of boswellic acid, a physiologically acceptable salt, a derivative, a salt of the derivative, a plant extract containing boswellic acid, or combinations thereof, administered to the organism is effective for preventing the destruction of functional tissue associated with the recited diseases. Furthermore, new claims 28 and 29 have been added, which recite methods for preventing the destruction of functional tissue associated with the recited diseases. Support for the amendments to claims 10 and 17, and new claims 28 and 29, may be found, at the very least, on page 5, lines 17-29, of the specification as filed. No new matter has been added by the present amendment.

Claims 10, 12-22, 24-25 and 27 have been rejected under 35 U.S.C. § 103 for purportedly being unpatentable over Ammon et al (EP 0 552 657) in combination of Mulshine et al (WO 95/24894) and Han (*Chin. Med. Sci. J.* 9(1):61-69 (1994)). For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

The claimed invention is drawn to methods for combating serious diseases, such as pulmonary emphysema, acute respiratory distress syndrome, shock lung, cystic fibrosis, chronic bronchitis, glomerulonephritis, rheumatoid arthritis, and for combating tumors and neoplasms or tumor metastases. These methods comprise administering to an organism boswellic acid, a physiologically acceptable salt, a derivative, a salt of the derivative, a

plant extract containing boswellic acid, or combinations thereof, in an amount effective for preventing the destruction of functional tissue associated with the various recited diseases and conditions.

As noted in the specification, leucocytic elastase plays an important part in the destruction of functional tissue associated with pulmonary emphysema, acute respiratory distress syndrome, shock lung, cystic fibrosis, chronic bronchitis, glomerulonephritis, rheumatoid arthritis, tumors and neoplasms and tumor metastases. Thus, by inhibiting leucocytic elastase one will prevent the destruction of functional tissue which is caused by this enzyme. The present inventors were the first to discover that boswellic acid could be used to inhibit leucocytic elastase, and thereby prevent the destruction of functional tissue and organs associated with these various diseases and conditions.

Ammon et al disclose the use of boswellic acid compounds for treating inflammation in diseases by inhibiting leukotrine synthesis. As noted previously, Ammon et al disclose treating "diseases of the joints (rheumatism)". Rheumatoid arthritis, which is treated by the claimed invention, is very different from other rheumatoid diseases. Rheumatoid arthritis is based on the destruction of the articular cartilage, which is in contrast to other rheumatoid diseases. This destruction leads to an irreversible deformation of the joint, which hinders movement. In the claimed invention, the boswellic acid is administered in an amount effective for preventing the destruction of functional tissue. Ammon et al does not disclose or suggest that boswellic acid can prevent the destruction of functional tissue, and therefore Ammon et al could not possibly disclose or suggest administering boswellic acid to an organism in an amount effective for preventing the destruction of functional tissue.

Applicants would also like to add that even if, as the Examiner contends, Ammon et al does disclose the use of boswellic acid for treating the same diseases as the claimed invention (which the applicants do not believe it does), such a disclosure would not render obvious the claimed invention. As pointed out, the claimed invention is drawn to a method which comprises administering to an organism boswellic acid, a physiologically acceptable salt, a derivative, a salt of the derivative, a plant extract containing boswellic acid, or combinations thereof, in an amount effective for preventing the destruction of functional tissue associated with the various recited diseases and conditions. Although such an effect may be inherent when one administers boswellic acid to an organism, “[t]hat which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.” *In re Spormann*, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966). Therefore, it would not be obvious, in view of Ammon et al, to administer an amount of boswellic acid which is sufficient for preventing the destruction of functional tissue, to treat the recited diseases. In light of this, claims 10, 12-22, 24, 25 and 27 are not obvious in view of Ammon et al.

Mulshine et al does not solve the deficiencies of Ammon et al. Mulshine et al discloses that lipxygenase inhibitor, i.e. inhibitors of 5-lipxygenase, can be used to treat epithelial cell-derived cancer. Mulshine et al provide evidence that three different 5-lipxygenase inhibitors exert cytotoxic actions in tumor cells. There is no suggestion that other inhibitors of 5-lipxygenase, such as boswellic acid, would have the same effect.

In addition, there is no suggestion provided by Mulshine et al to use boswellic acid in an amount sufficient to prevent destruction of functional tissue. In the claimed invention, the boswellic acid is administered in an amount effective for preventing the destruction of functional tissue. Mulshine et al does not disclose or suggest that boswellic acid (or any of the 5-lipoxygenase inhibitors used therein) can prevent the destruction of functional tissue, and therefore Mulshine et al could not possibly disclose or suggest administering boswellic acid to an organism in an amount effective for preventing the destruction of functional tissue.

Even if one were to assume that the use of the 5-lipoxygenase inhibitors by Mulshine et al would render obvious the use of boswellic acid (which applicants do not believe that it does), the use of boswellic acid in an amount effective for preventing functional tissue destruction would not be obvious, because, although such an effect may be inherent when one administers boswellic acid to an organism, “[t]hat which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.” *In re Spormann*, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966). Therefore, it would not be obvious, in view of either Ammon et al or Mulshine et al, to administer an amount of boswellic acid which is sufficient for preventing the destruction of functional tissue, to treat the recited diseases or tumors and neoplasms or tumor metastases. In light of this, claims 10, 12-22, 24, 25 and 27 are not obvious in view of Ammon et al or Mulshine et al, either taken alone or together.

Han does not solve the deficiencies of Ammon et al and Mulshine et al. Han does not disclose or suggest the use boswellic acid in an amount sufficient to prevent destruction of functional tissue. Although boswellic acid may inherently have this effect, that which is inherent is now known, and that which is not known can not be obvious. Therefore, it would not be obvious in view of Han to administer boswellic acid in an amount sufficient to prevent functional tissue destruction. In light of this, claims 10, 12-22, 24, 25 and 27 are not obvious in view of Ammon et al, Mulshine et al or Han, either taken alone or together.

At the very least, new claims 28 and 29 should be allowed. New claims 28 and 29 are drawn to methods of preventing the destruction of functional tissue. As noted above, there is no disclosure or suggestion in any of the cited references of a method for preventing the destruction of functional tissue. Thus, at the very least, new claims 28 and 29 should be allowed.

In light of these remarks, applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 103.

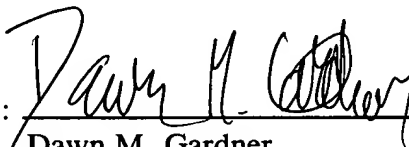
#### **CONCLUSION**

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited.

In the event that there are any questions relating to this application, the Examiner is invited to telephone the undersigned so that prosecution of the subject application may be expedited.

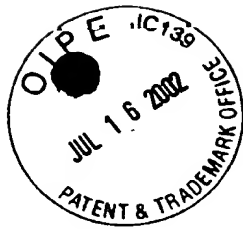
Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By:   
Dawn M. Gardner  
Registration No. 44,118

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(703) 836-6620

Date: July 16, 2002



**Attachment to Amendment and Reply dated July 17, 2002**

**Marked-up Claims 10 and 17**

10. (Four Times Amended) A method for combating diseases selected from the group consisting of pulmonary emphysema, acute respiratory distress syndrome, shock lung, cystic fibrosis (mucoviscidosis), chronic bronchitis, glomerulonephritis and rheumatoid arthritis, which are caused by increased leucocytic elastase or plasmin activity or can be treated by the inhibition of normal leucocytic elastase or plasmin activity, said method comprising administering [an effective amount of] boswellic acid, a physiologically acceptable salt, a derivative, a salt of the derivative, a plant extract containing boswellic acid, or combinations thereof, in an amount effective for preventing the destruction of functional tissue, to combat said diseases to a mammalian organism in need of such combating.

RECEIVED

JUL 18 2002

TECH CENTER 1600/2900

17. (Twice Amended) A method for combating tumors and neoplasms or tumor metastases which are caused by increased plasmin activity or can be treated by the inhibition of normal leucocytic elastase or plasmin activity, said method comprising administering [an effective amount of] boswellic acid, a physiologically acceptable salt, a derivative, a salt of the derivative, a plant extract containing boswellic acid, or combinations thereof, in an amount effective for preventing the destruction of functional tissue, to combat said tumors and neoplasms or tumor metastases to a mammalian organism in need of such combating.